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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,399	06/13/2005	Rajender Kumar Potlapally	DRF 33-010	3144
70554	7590	07/24/2008		
Reddy Us Therapeutics, Inc 3065 Northwoods Circle Norcross, GA 30071			EXAMINER TRUONG, TAMTHOM NGO	
			ART UNIT 1624	PAPER NUMBER
			MAIL DATE 07/24/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/507,399	Applicant(s) POTLAPALLY ET AL.	
	Examiner TAMTHOM N. TRUONG	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-61 is/are rejected.
- 7) ☒ Claim(s) 62 and 63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

NON-FINAL ACTION

The amendment of 2-29-08 has been fully considered. The amended claims 58-63 have overcome the previous rejection of 112/2nd paragraph. The argument on the 102 rejection is not found persuasive, and thus said rejection is maintained.

A review of the claims prompts new grounds of rejection.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Scope of Enablement:** Claims 58 and 61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process using particular solvents, does not reasonably provide enablement for a process using other organic solvents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The breadth of the claims;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;

- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The quantity of experimentation necessary;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The breadth of the claims: Claims 58 and 61 recite a process of making Formula I by first dissolve the free base in an "organic solvent". The term "organic solvent" includes at least more than two hundred chemical reagents as cited in Aldrich Solvents Library.

The amount of direction or guidance presented: The specification only provides 12 examples for the process of making Form I. Specific solvents used in those examples are: acetonitrile, xylene, methanol, ethanol, isopropanol, ethyl acetate, a mixture of acetone and xylene, dimethylformamide, 1,4-dioxane, a mixture of 1,4-dioxane and xylene, diethyl ketone, isobutylketone, and dimethylsulfoxide. Those solvents do not well represent the long list of solvents known in the art.

The state of the prior art: As evidence by **Lohray et. al.** (WO'097—cited previously), the Table on page 81 shows the sensitivity to polymorphs formed using different solvents. Thus, the state of the art does not support a process of making Form-I using any “organic solvent”.

The relative skill of those in the art: Even though the choice of solvents can be selected by one skilled in the art, the form of a polymorph cannot be predicted. Thus, the skilled chemist would still have to carry out undue experimentation to select an appropriate solvent for a particular form of polymorph.

The predictability or unpredictability of the art, and The quantity of experimentation necessary: The factor of unpredictability is shown by the teaching of **Lohray et. al.** With a limited examples provided, the skilled chemist would have to carry out undue experimentation to determine a polymorph formed by an “organic solvent” other than those taught in the disclosure.

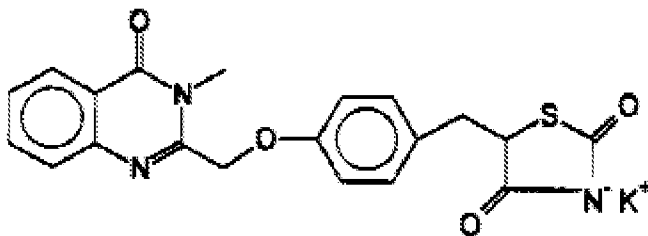
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 34 remains rejected under 35 U.S.C. 102(b) as being inherently anticipated by **Lohray et. al.** (WO 97/41097 or WO'097 – cited previously). On page 89, Lohray et. al. discloses the potassium salt of Glitzone shown below:



The disclosed salt has a melting point of 302°C which is indicative of a crystalline form

though the reference reveals no x-ray powder diffraction pattern.

Applicants argued that the crystalline form has DSC endotherms at 296.24°C and 307.64°C. It is not clear how this information relates to the actual melting point as two endotherms are reported not solely one, and multiple endotherms can occur based on rate of heating sample. Thus, this fact alone does not mean the disclosed potassium salt is not the same as herein. Applicants have not provided clear and convincing evidence to the contrary.

3. Claim 35-57 are rejected under 35 U.S.C. 102(b) as being inherently anticipated by **Lohray et. al.** (WO 97/41097 or WO'097 – cited previously). On page 5 of the instant disclosure, applicants admitted that Form I was made by the process in Example 41 of WO'097. Furthermore, the DSC on page 7 of the instant disclosure shows an endotherm at 301.17°C which is very close to the melting point (302°C) of Example 41 of WO'097.

4. Claims 35-57 are rejected under 35 U.S.C. 102(b) as being inherently anticipated by **Chebiyyam et. al.** (WO 00/15638 or WO'638 – cited previously).

Although new claims recite x-ray powder diffraction pattern for Form-I, the potassium salt in Example 39 of WO'638 is presumed to be Form-I because the process in Example 39 of WO'638 is virtually identical to the process in Example 2 of the instant disclosure, which produces Form-I. The same salt is added and the final product dried as was done in example 2. See also example 40.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Chebiyyam et. al.** (WO 00/15638 or WO'638 – cited previously).

Example 40 of WO'638 describes all essential steps. Although the reference's process has a slightly higher temperature range, the manipulation of temperature range is within routine experimentation of one skilled in this art. Also, the claim language is not limited to an exact temperature range i.e. "about 60-75°C" because the temperature of "about 75°C" can reasonably include 80°C, which is the lower end of Example 40 in WO'638. Furthermore, the MPEP states that changing temperature would be within the level of the skilled chemist for optimum yield.

See the following excerpt from MPEP:

Optimization Within Prior Art Conditions or Through Routine Experimentation

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference

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process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

2144.07 Art Recognized Suitability for an Intended Purpose

The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945) (Claims to a printing ink comprising a solvent having the vapor pressure characteristics of butyl carbitol so that the ink would not dry at room temperature but would dry quickly upon heating were held invalid over a reference teaching a printing ink made with a different solvent that was nonvolatile at room temperature but highly volatile when heated in view of an article which taught the desired boiling point and vapor pressure characteristics of a solvent for printing inks and a catalog teaching the boiling point and vapor pressure characteristics of butyl carbitol. “Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle.” 325 U.S. at 335, 65 USPQ at 301.).

See also In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960) (selection of a known plastic to make a container of a type made of plastics prior to the invention was held to be obvious); Ryco, Inc. v. Ag-Bag Corp., 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988) (Claimed agricultural bagging machine, which differed from a prior art machine only in that the brake means were hydraulically operated rather than mechanically operated, was held to be obvious over the prior art machine in view of references which disclosed hydraulic brakes for performing the same function, albeit in a different environment.).

Claim Objections

6. Claims 62 and 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base

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claim and any intervening claims. Claims 62 and 63 recite a process that use particular organic solvents such as: dimethylformamide, 1,4-dioxane, a mixture of 1,4-dioxane and xylene. Said solvents are not taught or fairly suggested by the prior art of record. Additionally, the first step is done at room temperature.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMTHOM N. TRUONG whose telephone number is (571)272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tamthom N. Truong/

Tamthom N. Truong
Examiner
Art Unit 1624

/Emily Bernhardt/
Primary Examiner, Art Unit 1624